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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,469	04/20/2001	William D. Huse	P-IX 4692	2981
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	L & FLORES LLP LA VILLAGE DRIVE		PONNALURI,	PADMASHRI
7TH FLOOR			ART UNIT	PAPER NUMBER
SAN DIEGO,	, CA 92122		1639	
			DATE MAILED: 11/16/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		09/839,469	HUSE ET AL.			
		Examiner	Art Unit			
		Padmashri Ponnaluri	1639			
Period f	The MAILING DATE of this communication or Reply	appears on the cover sheet with	the correspondence address			
THE - External control	MAILING DATE OF THIS COMMUNICATION IN THE PRIOR OF THE P	N. 1.136(a). In no event, however, may a repl reply within the statutory minimum of thirty (i od will apply and will expire SIX (6) MONTH tute, cause the application to become ABAN	ly be timely filed 30) days will be considered timely. 15 from the mailing date of this communication. NDONED (35 U.S.C. § 133).			
Status						
1) 🖂	Responsive to communication(s) filed on 07	' September 2004.				
2a) <u></u> □	This action is FINAL . 2b)⊠ T	his action is non-final.				
3)	Since this application is in condition for allow					
	closed in accordance with the practice unde	er <i>Ex parte Quayle</i> , 1935 C.D. 1	11, 453 O.G. 213.			
Disposit	ion of Claims					
4)⊠	Claim(s) 1-9 and 39-47 is/are pending in the	application.				
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	Claim(s) is/are allowed.					
	Claim(s) <u>1-9 and 39-47</u> is/are rejected.					
	Claim(s) is/are objected to.					
8)[_]	Claim(s) are subject to restriction and	d/or election requirement.				
Applicat	ion Papers					
9) 🗌	The specification is objected to by the Exami	ner.				
10)	The drawing(s) filed on is/are: a) a	ccepted or b) objected to by	the Examiner.			
	Applicant may not request that any objection to the		` ,			
	Replacement drawing sheet(s) including the corr					
11)	The oath or declaration is objected to by the	Examiner. Note the attached C	Office Action or form PTO-152.			
Priority (ınder 35 U.S.C. § 119	•				
12)	Acknowledgment is made of a claim for forei	gn priority under 35 U.S.C. § 1	19(a)-(d) or (f).			
	☐ All b) ☐ Some * c) ☐ None of:	. ,	(, (,			
	1. Certified copies of the priority docume	nts have been received.				
	2. Certified copies of the priority docume					
	3. Copies of the certified copies of the pr		ceived in this National Stage			
* 0	application from the International Bure	* * * * * * * * * * * * * * * * * * * *				
	See the attached detailed Office action for a li	st of the certified copies not red	ceived.			
Attachmen	t(s)					
	e of References Cited (PTO-892)	4) 🗍 Interview Sum	nmary (PTO-413)			
2) 🔲 Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/N	Mail Date			
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 r No(s)/Mail Date	8) 5) Notice of Infor 6) Other:	mal Patent Application (PTO-152)			

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DETAILED ACTION

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NOTE: The change of examiner in this application.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/7/04 has been entered.

- 2. The after-final amendment filed on 2/12/04 has been fully considered and entered into the application.
- 3. Claims 39-47 have been added and claim 5 has been amended by the after-final amendment filed on 2/12/04. Claims 1-9 and 39-47 are currently pending and are examined in this application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9, 39-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

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The instant claims briefly recite a method for determining binding of a receptor to one or more ligands comprising contacting a collective receptor variant population with said one or more ligands and detecting binding of said one or more ligands to said collective receptor variant population.

To satisfy the written description requirement, an applicant may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

The instant specification discloses that 'receptor' is capable of selectively binding to a ligand, and is generally macromolecules such as polypeptides, nucleic acids, carbohydrates or lipid; 'ligand' refers to a molecule selectively bind to a receptor, and the ligand can be any type of molecule such as polypeptide, nucleic acid, carbohydrate, lipid or any organic derived compound; and the further the specification discloses ligand can be a receptor and conversely, a molecule that is a receptor can also be a ligand since ligands and receptors are defined as binding partners. The specification discloses that the 'variant' is molecule that shares **similar** structure and function; and 'optimal binding' characteristics will depend on the particular application of the binding molecule.

The specification example discloses that the parent receptor is a mouse monoclonal antibody, and six variant receptors were generated and screened for binding to anti-idiotypic antibody ligands. The specification has no other examples of ligands, receptors or variants of receptors. The specification has not disclosed methods in which the receptor variant population is divided into subpopulations. The specification discloses hypothetical methods, in which the receptor variant population can be screened by dividing ligand population into sub-populations o

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or individual ligands to determine the binding activity [see 0016]. The specification has not disclosed oligonucleotide or carbohydrarte or lipid or organic molecule as 'ligand' or 'receptor.' The specification discloses general methods for expressing the receptor variants in melanophore cells (example I). The specification has not disclosed the receptor variant which binds to a ligand identified by the claimed method. The specification discloses general methods of identifying a receptor sequence which specifically binds to a ligand, and methods of generating variants of the receptor recombinantly, and methods of screening for the variant.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Thus, it requires a representative sample of compounds (i.e., receptor, ligand) or a showing of sufficient characteristics to demonstrate possession of the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (see MPEP 2163).

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The instant specification discloses general hypothetical methods in which binding partners can be identified. The specification has no working examples other than the mouse monoclonal antibody variants and anti-idiotypic antibody which binds to it as ligands and receptors.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

In the present instance, the claimed invention contains no identifying characteristics regarding the receptors, ligands or the receptor variant, except the generic definitions. The variant receptors have to be prepared and further screened to identify the variant, which binds to the ligand, thus the variants have to be prepared. The specification has not disclosed which peptides, polynucleotides, carbohydrates, or organic molecules have the 'optimal binding activity', and in absence of teachings in the specification the claimed method can not be said to have been described adequately.

6. Claims 5 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The limitation 'optimal binding activity to said one or more ligands relative to a parent

receptor of said receptor variant population' claimed in claims 5, 43 has no clear support in the specification and the claims as originally filed. The subject matter claimed in claims 5 and 43broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 1-9, 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 39 vague indefinite by reciting 'method for determining binding of a receptor to one or more ligands.....and detecting binding of said one or more ligands to said collective receptor variant population. It is not clear if according to the method steps how 'binding of one or more ligands to said collective receptor variant population' (a group receptors or a library) would lead to determining binding of a single receptor to one or more ligands. The claimed method is either missing a method step or the method is intend to identify the entire population of receptors or a library of receptors which bind to the ligand. Applicants are requested to clarify.

Claims 2 and 40 recite 'further comprising dividing said collective receptor variant population into two or more sub-populations...', it is not clear whether applicants mean that the collective receptor variant population is the one is bound to the one or more ligands (the positive

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population) or the original collective receptor variant population irrespective of its binding to the ligand. Applicants are requested clarify which population of the receptor variant population is divided.

Claim 39 recites the limitation "said collective receptor variant population' in line 3.

There is insufficient antecedent basis for this limitation in the claim.

Claims 5 and 43 are vague and indefinite by reciting 'optimal binding activity', which is a relative term. The specification disclosure of the term has various different meanings, and none would read on the instant claimed limitations. And the specification has not disclosed the 'optimal bindingrelative to a parent receptor of said receptor variant population.'

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 10. Claims 1-8, 39-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,426,856 (Lerner et al).

The instant claims briefly recite a method for determining binding of a receptor to one or more ligands comprising contacting a collective receptor variant population with said one or

more ligands and detecting binding of said one or more ligands to said collective receptor variant population.

In the claims the terms 'ligand' and 'receptor' are considered as binding partners, and the further the ligand can be a receptor and conversely, a molecule that is a receptor can also be a ligand since ligands and receptors are defined as binding partners in the specification.

Lerner et al disclose a method for identifying a chemical that acts as an agonist for G protein coupled cell surface receptor (i.e., see abstract). The method uses expression of the receptors in pigment cells, specifically melanophores (i.e., see column 13, lines 54-67, example 6) (refers to instant claim recombinantly expressed in melanophores). Lerner et al discloses a multiplicity of GPC receptors that are expressed (i.e., see column 14, lines 31-49, column 15). The reference clearly teaches cloning of new GPC receptors (refers to receptor variant population of the instant claims). Lerner et al teach a variety of bioassays that can be used to screen the GPC receptors for binding to ligands (i.e., see examples 1-5) (refers to the instant claimed method). The reference also teaches a method for isolating a clone for a GPC receptor via a fractionation procedure (i.e., see columns 18-19). The reference specifically discloses a procedure in which colonies are tested, then subdivided into smaller pools based on positive results where each sub set is retested until a single clone is identified (refers to instant claim dividing the population into sub-populations and repeating the dividing and detecting). Thus, the reference clearly anticipates the claimed invention.

Claims 1-5, 8-9, 39-43, 46-47 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,287,787 B1 (Houghten et al, filing date November 24, 1993).

The instant claims briefly recite a method for determining binding of a receptor to one or more ligands comprising contacting a collective receptor variant population with said one or more ligands and detecting binding of said one or more ligands to said collective receptor variant population.

In the claims the terms 'ligand' and 'receptor' are considered as binding partners, and the further the ligand can be a receptor and conversely, a molecule that is a receptor can also be a ligand since ligands and receptors are defined as binding partners in the specification.

Houghten et al teach dimeric oligopeptide mixture sets (refers to the receptor variants or sub-population of receptor variants of the instant claims). Houghten discloses a library of dimeric oligopeptide mixture sets that comprise a plurality of sets of dimmer oligomer mixtures (i.e., see column 8). The reference teaches each set of the library has same length, position of mercapto residue in the chain, and each set in the library differs from the other sets by the position of one or more predetermined amino acid residue, or the identity of one or more predetermined amino acid residue (refers to the variant receptor population of the instant claims) (i.e., see column 8). The reference discloses a process for determining the sequence of a dimeric oligopeptide ligand (considered as receptor) that preferentially binds to an acceptor (considered as ligand). The method comprises a library of dimeric oligopeptide sets is admixed with an acceptor, and the binding of each set exhibiting preferential binding relative to the other set is determined, thereby identifying the amino acid sequence of the ligand (i.e., see column 8) (refers to the instant claimed method). The reference discloses that the method is repeated with each set of library. The reference teaches that the individual library sets exhibit preferential binding compared to the library used immediately before (refers to the instant claim 'optimal binding activity') (i.e., see

column 9). The reference discloses that the dimeric oligopeptide mixture set to include either a radio active label or a photoreactive label (refers to instant claim identifiable tag) (i.e. see column 24). The reference discloses 190 dimer mixture sets, and screening those 190 sets using a binding assay. Houghten et al further disclose positional scanning assay, in which six groups of precursors molecules prepared, and each group also contained 19 different sub-group mixtures of oligopeptides, and each sub-group mixture within each group members of the group form six libraries of dimeric oligopeptide mixtures (refers to instant claim dividing said collective receptor variant population) (i.e., see example 6). The reference clearly anticipates the claimed invention.

12. Claims 1, 6-7, 9, 39, 44-45, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,912,335 (Bergsma et al, filing date October 03, 1996).

The instant claims briefly recite a method for determining binding of a receptor to one or more ligands comprising contacting a collective receptor variant population with said one or more ligands and detecting binding of said one or more ligands to said collective receptor variant population.

In the claims the terms 'ligand' and 'receptor' are considered as binding partners, and the further the ligand can be a receptor and conversely, a molecule that is a receptor can also be a ligand since ligands and receptors are defined as binding partners in the specification.

Bergsma et al teach novel human G-protein coupled receptors, referred as HUVCT36 polypeptides, variants, and process of making the polypeptides. Bergsma et al teach methods of screening for compounds which bind to and activate or inhibit activation of the receptor polypeptides of the invention. The reference teaches that the 'variant polypeptides' include

polypeptides which differ in amino acid sequence from another, reference polypeptide (refers to the receptor variant of the instant claims) (i.e., see column 10); and 'binding molecules' refer to molecules, including ligands that specifically bind to or interact with receptor polypeptides of the present invention (refers to the ligands of the instant claims) (I.e., see column 11). Bergsma et al teach polynucleotide encoding amino acid sequence of HUVCT36 set out in FIGS. 1A, 1B and 1c; variants, analogs, derivatives and fragments (refers to the population of receptor variant population of the instant claims). The reference teaches that vectors which include polynucleotides, which encode HUVCT36 and variants, and host cells which are genetically engineered with vectors of the invention and production of polypeptides of the invention by recombinant techniques (refers to 'recombinantly expressed in cells' of the instant claims) (i.e., see column 18). The reference teaches variety expression vectors to be used with the invention (i.e., see column 19). The reference teaches that the vectors generally include selectable markers.

Bergsma et al teach HUVCT36 binding molecules and assays to identify the binding molecules to HUVCT36 (i.e., see columns 29-31). The reference teaches that HUVCT36 receptor expressed in a mammalian or eukaryotic and/or yeast cells and used to screen complex biological mixtures, compound banks, and combinatorial peptide and/or organic libraries for natural and surrogate ligands, which are agonistic, and/or antagonists. In one embodiment the reference teaches that method for screening of peptide libraries for binding partners.

Recombinant tagged or labeled HUVCT36 is used to select peptides from a peptide or phosphopepetide library, which interact with HUVCT36. And further the reference teaches one screening procedure includes the use of melanophores (refers to instant claims 'recombinantly expressed in melanophores') which are transfected to express the HUVCT36 of the invention to

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screen for test compound to observe binding, stimulation and inhibition of the functional aspect (i.e., see column 31). The reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

- 13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 15. Claims 1-9, 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,912,335 (Bergsma et al) and US patent 5,844,094 (Hudson et al).

The instant claims briefly recite a method for determining binding of a receptor to one or more ligands comprising contacting a collective receptor variant population with said one or more ligands and detecting binding of said one or more ligands to said collective receptor variant population.

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In the claims the terms 'ligand' and 'receptor' are considered as binding partners, and the further the ligand can be a receptor and conversely, a molecule that is a receptor can also be a ligand since ligands and receptors are defined as binding partners in the specification.

Bergsma et al teach novel human G-protein coupled receptors, referred as HUVCT36 polypeptides, variants, and process of making the polypeptides. Bergsma et al teach methods of screening for compounds which bind to and activate or inhibit activation of the receptor polypeptides of the invention. The reference teaches that the 'variant polypeptides' include polypeptides which differ in amino acid sequence from another, reference polypeptide (refers to the receptor variant of the instant claims) (i.e., see column 10); and 'binding molecules' refer to molecules, including ligands that specifically bind to or interact with receptor polypeptides of the present invention (refers to the ligands of the instant claims) (I.e., see column 11). Bergsma et al teach polynucleotide encoding amino acid sequence of HUVCT36 set out in FIGS. 1A, 1B and 1c; variants, analogs, derivatives and fragments (refers to the population of receptor variant population of the instant claims). The reference teaches that vectors which include polynucleotides, which encode HUVCT36 and variants, and host cells which are genetically engineered with vectors of the invention and production of polypeptides of the invention by recombinant techniques (refers to 'recombinantly expressed in cells' of the instant claims) (i.e., see column 18). The reference teaches variety expression vectors to be used with the invention (i.e., see column 19). The reference teaches that the vectors generally include selectable markers.

Bergsma et al teach HUVCT36 binding molecules and assays to identify the binding molecules to HUVCT36 (i.e., see columns 29-31). The reference teaches that HUVCT36 receptor expressed in a mammalian or eukaryotic and/or yeast cells and used to screen complex

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biological mixtures, compound banks, and combinatorial peptide and/or organic libraries for natural and surrogate ligands, which are agonistic, and/or antagonists. In one embodiment the reference teaches that method for screening of peptide libraries for binsding partners.

Recombinant tagged or labeled HUVCT36 is used to select peptides from a peptide or phosphopepetide library, which interact with HUVCT36. And further the reference teaches one screening procedure includes the use of melanophores (refers to instant claims 'recombinantly expressed in melanophores') which are transfected to express the HUVCT36 of the invention to screen for test compound to observe binding, stimulation and inhibition of the functional aspect (i.e., see column 31).

The claimed invention differs from the prior art teachings by reciting 'dividing said collective receptor variant population into two or more subpopulation and contacting the subpopulation with a ligand...' Bergsma et al teach HUVCT36 binding molecules and assays to identify the binding molecules to HUVCT36 (i.e., see columns 29-31). The reference teaches that HUVCT36 receptor expressed in a mammalian or eukaryotic and/or yeast cells and used to screen complex biological mixtures, compound banks, and combinatorial peptide and/or organic libraries for natural and surrogate ligands, which are agonistic and/or antagonists. Bergsma et al do not teach dividing the receptor variant population into sub-populations and detecting the subpopulation which binds to the ligand. It is obvious to one skilled in the art of recombinant technology to do multiple rounds of screening or panning to identify the affinity ligands or specific binding pairs, in panning the phage displaying the ligands which bind to the receptor of interest are further subjected to panning or screening. Hudson et al teach methods for production of novel polypeptides with enhanced or modified binding activity or specificity to antigens. The

reference teaches recombinant antibody-like molecules (receptor variant population of the instant

claims). The reference teaches DNA constructs (phage display libraries) encoding the target-

binding polypeptide, selecting a sub-population of display vectors displaying target binding

polypeptides (refers to instant claim dividing the population into sub-populations), subjecting the

selected sub-populations to one or more cycles of mutagenesis and selection in order to obtain a

sub-population of display vectors displaying target binding polypeptides (i.e., see columns 3-5).

Thus, it would have been obvious to one skilled in the art at the time the invention was made to

use repeated detection steps or serial of screening steps with various sub-populations of the

initial library or population. A person skilled in the art would have been motivated to do so

because modified or increased affinity ligands would be obtained by the serial screening of the

library of ligands.

Response to Arguments

16. Applicant's arguments filed on 2/12/04 with respect to claims 1-9 have been considered

but are moot in view of the new ground(s) of rejection and further the advisory action mailed on

3/24/04 has addressed the arguments.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809.

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The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri Primary Examiner Art Unit 1639

November 15, 2004

PANMASHRI PONNALURI BRIMARY EXAMINER